K011132

JUN - 8 2001

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife® HEPA Filter

Manufacturer:	Allegiance Healthcare Corporation 1660 Iowa Avenue Riverside, CA 92507
Regulatory Affairs Contact:	Sharon Robbins 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3311
Date Summary Prepared:	April, 2001
Common Name:	Airlife ® HEPA Filter
Classification:	Class II per 21CFR § 868. 5260
Predicate Device:	American Two Way Bacterial/Viral Retentive Filter
Description:	The Airlife Breathing Circuit Bacterial Filter is a bi-directional breathing device used to reduce the transmission of microorganisms in gases delivered to and exhaled from patients and breathing systems. The device contains a pleated filter media that is polypropylene based media. The filter media is housed in a clear shell.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife®HEPA Filter

Intended Use:	Breathing Circuit Bacterial Filter is a device intended to remove microbiological and PM from gases in the breathing circuit.
Substantial Equivalence:	The Airlife®Breathing Circuit Bacterial Filter is substantially equivalent to the American Two Way Bacterial/Viral Retentive Filter in that: - the intended use is the same - the performance attributes are similar
Summary of testing:	All materials used in the fabrication of the Airlife® HEPA Filter were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 " Biological Evaluation of Medical Devices" . These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Ms. Sharon Robbins
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085-6787

Re: K011132
Airlife® HEPA Filter
Regulation Number: 868.5260
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: May 18, 2001
Received: May 25, 2001

Dear Ms. Robbins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

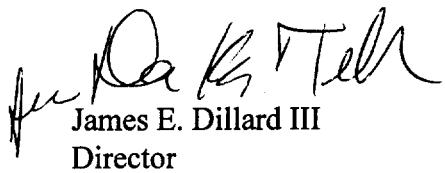
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

Allegiance Healthcare Corporation
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510(k) Number (if known): K011132

Device Name: Airlife ® HEPA FIlter

Indications For Use: Breathing Circuit Bacterial Filter is a device intended to remove microbiological and particulate matter from gases in the breathing circuit.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011132

Prescription Use ✓ or Over-The Counter Use ____
(Per 21 CFR 801.109)